University of North Carolina at Chapel Hill
Consent for Storing Biological Specimens With Identifying Information

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IRB Study # 09-1344
Consent Form Version Date: 11/23/11

Title of Study: Cardiopulmonary Responses to Exposure to Ozone and Diesel Exhaust with Moderate Exercise in Healthy Adults

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What are some general things you should know about research?
Research is designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from participating. There also may be risks.

You may refuse to take part in research.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this specimen repository or "biobank?"
Research with blood, tissue, cells or body fluids (specimens) can help researchers understand how the human body works. Research can also answer other questions by using specimens. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future,

research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or "biobank."

All specimens for this study will be labeled with your study subject number that does not include personal identification information and will be stored in a repository where only project members will have access to the specimens. There is a need to store specimens in such a repository because this will be an ongoing study where specimens from subjects will be collected over an extended period of time. Storing of specimens allows for all specimens to be processed at the same time.

It also makes it possible to keep any remaining specimens in our biobank indefinitely and allows our scientists the opportunity to further study these specimens with as yet unknown questions and techniques. Research studies and questions in which the specimens may be used have not yet been determined. These studies may involve genetic research. Genetic research is about finding the specific location of genes, learning how genes work, and investigating relationships between a certain gene and the environment or people's habits and diets, and different diseases.

How will the specimens be collected?
Your specimens will be collected during the research study listed on the first page of this consent. No additional specimens will be collected from you.

What will happen to the specimens?
Study specimens will be stored in a secure room with restricted access at the U.S. Environmental Protection Agency Human Studies Facility located in Chapel Hill, North Carolina. The specimen will be prepared, labeled with the study subject identification number, and stored indefinitely in a freezer for future testing under *IRB# 07-1768, Repository for Storage of Human Specimens*. Names of subjects associated with ID numbers will be archived and locked; only medical and scientific personnel directly associated with this study will have access to this information. No personal identifying information will be attached to the biologic fluid specimen. Portions of the specimen may be shared with researchers at other scientific institutions, however, only coded specimens will be sent and the investigator will employ a data use agreement. Under no circumstances will any identifying information be sent along with specimens. The decision to destroy the specimens may be made by the investigator or by you if you notify the investigator in writing that you no longer want the specimens stored.

What are the possible benefits to you?
Benefits to you are unlikely. Research is designed to benefit society by gaining new knowledge. You will not benefit personally from having your specimens stored in this biobank.

What are the possible risks or discomforts involved with the use of your specimens?

Risk of breach of confidentiality is minimal. You will be assigned a study number which will be used for data – not your name. The study number is all that will be entered into computer databases. All paper files which may contain your name or screening number are secure in locked file cabinets in the EPA building which has limited access 24 hours/day. A numeric coding system will be used to ensure that you cannot be directly identified from the specimens alone. If we collect genetic information from the stored specimens, there is also a potential risk for some of your relatives and other members of your ethnic group, since they share some of your genetic makeup.

Will there be any cost to you for storage of the specimens?

There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for the use of your specimens?

You will not receive any additional compensation for having your specimens stored in this biobank.

Who owns the specimens?

Any blood, body fluids, cell or tissue specimens obtained for the purpose of this study become the exclusive property of The U.S. Environmental Protection Agency and will be stored under *IRB# 07-1768, Repository for Storage of Human Specimens*. The researchers may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will your privacy be protected?

You will be assigned a study identification number. Names of subjects associated with ID numbers will be archived and locked; only medical and scientific personnel associated with this study will have access to this information. No personal identifying information will be attached and/or recorded in the data log sheets, biologic specimens, or electronic data sets. No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the U.S. Environmental Protection Agency and UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Study specimens will be stored in a secure room with restricted access. The sample will be prepared and stored indefinitely in a freezer for future testing. Portions of the specimens may be shared with researchers at other scientific institutions, however, only coded specimens will be sent. Under no circumstances will any identifying information be sent along with specimens to outside investigators. All medical records generated during this study will be kept in the medical records office at the EPA Human Studies Facility. The Medical Station is locked when not

attended by study staff, and the EPA Human Studies Facility has limited access to authorized individuals only, 24 hours/day for 7 days/week.

If genetic information is obtained from your stored specimens, A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Will researchers seek approval from you to do future studies involving the specimens?
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. In some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

Will you receive results from research involving your specimens?
Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

Can you withdraw the specimens from the research repository?
If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your remaining specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

What will happen if you are injured by this research?
All forms of human health research involve some risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due to participating in this study. If you develop an injury or illness determined by an appointed US EPA physician to be due to your participation in this research, the US EPA will reimburse your medical expenses to treat the injury or illness up to $5000. If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. Seq., provides for money damages against the United States when personal injury or property loss results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this

consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence.

If a research related injury or illness occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at (919) 966-6217.

Who is sponsoring this research?
This research is funded by the United States Environmental Protection Agency. Several of the investigators including the Principal Investigator are federal employees. The researchers do not, however, have a direct financial interest in the final results of the study.

What if you have questions about this research?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB_ subjects@unc.edu. You may also contact the Director of the EPA NHEERL Human Research Protocol Office at 919-966-6217.

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Principle investigator: Michael Madden, PhD

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored with the identifying code(s).

Signature of Research Subject _____ Date _____

Printed Name of Research Subject _____

Signature of Research Team Member Obtaining Consent _____ Date _____

Printed Name of Research Team Member Obtaining Consent _____